Serial No. 09/920,267 Docket No. Cen249 By: KD

Application of: Jill Giles-Komar et al Mailed: November 2-2006

Entitled: Anti-Integrin Antibodies, Compositions, Methods AND Uses

THE FOLLOWING HAS BEEN RECEIVED IN THE U.S. PATENT OFFICE ON THE DATE STAMPED HEREON:

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- ☐ Assignment
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- ☐ Fee Transmittal
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- ☒ Amendment
- ☐ Extension of Time
- ☐ Issue Fee Transmittal
- ☐ PCT Filing _____
- ☐ IDS-Form 1449
- ☐ Drawings ___ sheets
- ☐ MPEP 609/_____
- ☐ Notice of Appeal
- ☐ Brief
- ☐ Priority Document
- ☐ Status Inquiry
- ☐ Sequence Listings/Diskette
- ☐ Biological Deposit Declaration
- ☒ Other Postcard
- ☒ Office Action (10/16/06)

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,267	08/01/2001	George Heavner	CEN 249	5698

27777 7590 10/16/2006

PHILIP S. JOHNSON
JOHNSON & JOHNSON
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NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,267	HEAVNER ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-8,24-28 and 102-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *24,25,102 and 103* is/are allowed.

6)☒ Claim(s) *4-8,26-28 and 104-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/9/02, 11/13/02&2/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 4-8, 24-28 and 102-110 are pending.

2. Applicant's election without traverse of Group II, claims 4-8,24-48, 64-68 and 84-88 (now claims 4-8, 24-28 and 102-110) drawn to an isolated nucleic acid encoding a monoclonal antibody which binds to anti-dual integrin, vectors, host cells and methods of producing filed on 8/15/06, is acknowledged.

4. Claims 4-8, 24-28 and 102-110 are under examination as they read on an isolated nucleic acid encoding a monoclonal antibody, which binds to anti-dual integrin, vectors, host cells and methods of producing.

4. Applicant's IDS, filed 7/9/02, 11/13/02 and 2/14/06, is acknowledged. The International Search Report (filed 11/13/02) was crossed out but the references listed thereon had been considered.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7, 27 and 105 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The recitations "653" and "293" in claims 7, 27 and 105 are indefinite, they only describe the host cells of interest by an arbitrary number name, "653" and "293". There is nothing in the claims which distinctly identify the host cells.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 4-8, 26-28 and 104-106 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a human monoclonal antibody comprising human heavy chain of SEQ ID NO: 7 and human light chain variable regions of SEQ ID NO:8, or an isolated nucleic acid encoding an isolated mammalian anti-dual integrin antibody comprising (i) all of the heavy chain CDR amino acid sequences of SEQ ID NOs: 1-3 and (ii) all of the light chain CDR amino acids sequences of SEQ ID NOs:4-6, does not reasonably provide enablement for an isolated nucleic acid encoding at least one isolated mammalian anti-dual integrin antibody having at least one variable region comprising SEQ ID NO: 7 or 8 in claim 4, A prokaryotic or eukaryotic host cell comprising an isolated nucleic acid in claims 26 and 104, a host cell, wherein the host cell is "653", "293", "any derivative", any

immortalized or transformed cell" in claims 7, 27, and 105, or a method for producing at least one anti-dual integrin antibody comprising translating a nucleic acid in vitro, in vivo or "in situ" in claims 8, 28 and 106. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There is insufficient guidance and direction as to make and use mammalian antibodies comprising the VH of SEQ ID NO: 7 or VL of SEQ ID NO:8.. However, it is well established in the art that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. The amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity which is characteristic of the parent immunoglobulin. It is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al (Proc Natl Acad Sci USA 1982 Vol 79 page 1979). Rudikoff et al. teach that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. It is unlikely that mammalian antibody as defined by the claims which may contain less than the full heavy and light chain variable regions of an CNTO 95 have the required binding function. Undue experimentation would be required to produce the invention commensurate with the scope of the claims from the written disclosure alone. Further evidence came from the 20030143603 which teaches that anti-tumor necrosis factor antibody light chain variable region comprising the claimed SEQ ID NO: 8 (see published SEQ ID NO: 8), providing evidence that the formation of an intact antigen-binding site requires the association of the complete heavy and light chain variable regions of a CNTO 95 antibody are required for the binding function. Therefor, an antibody that comprising at least one variable region comprising SEQ ID NO: 7 or 8 would not result in an anti-alpha-V binding antibody.

Claims 26 and 104, which depend form claims 24 and 102, respectively, recite a host cell that comprises only a nucleic acid lack a vector comprises a DNA sequence that contains a gene under the control of or operatively linked to a regulatory element, for example a promoter. It cannot be seen how the human anti-dual integrin antibody gene would be amplify and translated in the claimed host cell. It appears that claims 26 and 104 should depend form claims 25 and 103, respectively.

Claims 7, 27, and 105 fail to establish the structure of "653", "293", "any derivative, immortalized or transformed" cell. "653", "293", are arbitrary cell line names. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of "653", "293" host cell broadly encompassed by the claims. Further, It

is noted that the recited cell lines are already "immortalized or transformed", accordingly it is unclear how those cells would be further "immortalized or transformed". Finally, the specification was not found to provide sufficient guidance to the skilled artisan as to how to make and use host cell "derivatives" commensurate in scope with the instant claims. The specification fails to provide guidance on the claimed host cell's "derivatives". The claims as written encompass a broad genus of host cell with an unlimited number of possibilities. Further, the enablement issues of making the host cell derivatives still remain because the specification does not teach and provide sufficient guidance how to make such "derivatives".

Similarly, claims 8, 28 and 106 recite a method of producing at least one anti-dual integrin antibody comprising translating the claimed nucleic acid in vitro, in vivo or in situ. However, in order for the antibody to be produced in vivo or in vitro (using the claimed host cells) the claimed nucleic acid has to be under the control of a vector. Therefore, the claimed method for producing the claimed antibody would not work because the coding region is not operably linked to a promoter capable of directing expression of the claimed nucleic acid (facilitating translation). Finally, it is unclear as to how to use in situ methods to produce the claimed antibodies. Is the in situ method read on a single cell production of the claimed antibody?

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Claims 24-25 and 102-103 are allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 26, 2006

Maher Haddad

Maher Haddad, Ph.D.
Primary Examiner
Technology Center 1600

SUBMISSION UNDER MPEP 609 D

Application Number	09/920,267
Filing Date	AUGUST 1, 2001
First Named Inventor	JILL GILES-KOMAR
Group Art Unit	
Examiner Name	
Attorney Docket Number	CEN249

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Name of Patentee or Applicant of Cited Document	U.S. Patent Document Number	Kind Code[2] (if known)	Pages, Columns, Lines, where relevant passages or relevant figures appear

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Name of Patentee or Applicant of Cited Document	Foreign Patent Document Office[3]	Number[4]	KindCode[5]	Pages, Columns, Lines, where relevant passages or relevant figures appear	T[6]

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
MH		MITJANS et al, "In Vivo Therapy of Malignant Melanoma by Means of Antagonists of αv Integrins," Int. J. Cancer, 2000, pp 716-723, Vol. 87, Wiley-Liss, Inc., Spain.	
MH		MITJANS et al, "An anti-αv-integrin antibody that blocks integrin function inhibits the development of a human melanoma in nude mice," Journal of Cell Science, 1995, pp 2825-2838, Vol. 108, The Company of Biologists Limited, Great Britain.	
MH		CASEL et al, "RGD Peptides and Monoclonal Antibodies, Antagonists of α_v-Integrin, Enter the Cells by Independent Endocytic Pathways," Laboratory Investigation, 2001, pp 1615-1626, Vol. 81, No. 12, The United States and Canadian Academy of Pathology, Inc., USA.	

Examiner Signature	/Maher Haddad/	Date Considered	09/26/2006

PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Application Number	09/920,267
Filing Date	August 1, 2001
First Named Inventor	Giles-Komar, Jill
Group Art Unit	1645
Examiner Name	Not yet assigned
Attorney Docket Number	CEN-249

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear

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MH		WO	0031248	A	Smithkline Beecham Corp.	06-02-2000		
MH		WO	0044404	A	Children's Hospital Los Angeles	08-03-2000		

Examiner Signature	/Maher Haddad/	Date Considered	09/26/2006

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MH		TAM, S., et al.: "Abciximab (ReoPro, chimeric 7E3 Fab) demonstrates equivalent affinity and functional blockade of glycoprotein IIB/IIIa and alpha (v) beta2 integrins". vol. 98, no. 11, 09-15-1998, pgs. 1085-1091, XP000882678.	
MH		TRIKHA, M. et al.: "A potential new application for a cardiovascular drug: Role for ReoPro (Abciximab), an inhibitor of gpIIb/IIIa and alphaVbeta3 integrins, as an anti-cancer agent". Proceedings of the American Association for Cancer Research, vol. 41, March 2000, page 577, XP002212901.	
MH		SUZUKI, S., et al.: "cDNA and amino acid sequences of the cell adhesion protein receptor recognizing vitronectin reveal a transmembrane domain and homologies with other adhesion protein receptors". Proceedings of the National Academy of Sciences of the U.S.A., vol. 83, no. 22, November 1986, pgs. 8614-8618, XP002212902.	

Examiner Signature	/Maher Haddad/	Date Considered	09/26/2006

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SUBMISSION UNDER MPEP 609 D

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MH		~~PCT International Search Report, PCT/US01/24784, September 29, 2002.~~	

Examiner Signature	/Maher Haddad/	Date Considered	09/26/2006

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Sheet 1 of 2

Application Number	09/920,267
Filing Date	08/01/2001
First Named Inventor	Jill Giles-Komar et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	CEN0249

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear
MH		5,674,483		Yuan-Po Tu et al.	10/07/1997	
		5,985,278		Francesc Miljans et al.	11/16/1999	
		6,369,204 B1		Kyung Jin Kim et al.	04/09/2002	
		6,359,126 B1		Kyung Jin Kim et al.	03/19/2002	
		6,171,588 B1		Christopher P. Carron et al.	01/09/2001	
MH		2001/0011125 A1		William D. Huse	08/02/2001	

FOREIGN PATENT DOCUMENTS

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MH		WO	WO95/25543	A1	Scripps Research Institute	09/28/1995		
MH		WO	WO97/06791	A1	Scripps Research Institute	02/27/1997		
MH		WO	WO97/38859	A1	G. D. Searle & Co.	10/09/1997		
MH		WO	WO93/20229	A1	Genentech, Inc.	10/14/1993		
MH		EP	EP0 719859	A1	Merck Patent GMBH	07/03/1996		
MH		WO	WO94/12181	A1	Merck & Co., Inc.	06/09/1994		

Examiner Signature	/Maher Haddad/	Date Considered	09/26/2006

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[1] Unique citation designation number. [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if

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MH		GUNTHER GASTL, THOMAS HERMANN, MICHAEL STEURER, JORG ZMIJA, EBERHARD GUNSILIUS, CLEMENS UNGER, AND ANDREA KRAFT, "Angiogenesis as a target for tumor treatment", Oncology, 1997, 177-84, vol. 54.	
		BRIAN P. ELICEIRI AND DAVID A. CHERESH, "The Role of alpha-v integrins during angiogenesis: insights into potential mechanisms of action and clinical development", The Journal of Clinical Investigation, May 1999, 1227-30, vol. 103, no. 9.	
		MARTIN FRIEDLANDER, PETER C. BROOKS, ROBERT W. SHAFFER, CHRISTINE M. KINCAID, JUDITH A. VARNER, AND DAVID A. CHERESH, "Definition of two angiogenic pathways by distinct alpha-v integrins", Science, Dec. 1 1995, 1500-2, vol. 270.	
		LISA D. TAYLOR, CONDIE E. CARMACK, DENNIS HUSZAR, KAY M. HIGGINS, ROSHANAK MASHAYEKH, GETACHEW SEQUAR, STEPHEN R. SCHRAMM, CHIUNG-CHI KUO, SUSAN L. O'DONNELL, ROBERT M. KAY, CLIVE S. WOODHOUSE, AND NILS LONBERG, "Human immunoglobulin transgenes undergo rearrangement, somatic mutation and class switching in mice that lack endogenous IgM", International Immunology, 1994; 579-91, vol. 6, no. 4, Oxford University Press.	
		NILS LONBERG, LISA D. TAYLOR, FIONA A. HARDING, MARY TROUNSTINE, KAY M. HIGGINS, STEPHEN R. SCHRAMM, CHIUNG-CHI KUO, ROSHANAK MASHAYEKH, KATHRYN WYMORE, JAMES G. MCCABE, DONNA MUNOZ-O'REGAN, SUSAN L. O'DONNELL, ELIZABETH S. G. LAPACHET, TASHA BENGOECHEA, DIANNE M. FISHWILD, CONDIE E. CARMACK, ROBERT M. KAY, AND DENNIS HUSZAR, "Antigen-specific human antibodies from mice comprising four distinct genetic modifications", Nature, Apr. 28 1994, 856-9, vol. 368.	
		MICHAEL NEUBERGER, "Generating high-avidity human Mabs in mice", Nature Biotechnology, July 1996, 826, vol. 14.	
		DIANNE M. FISHWILD, SUSAN L. O'DONNELL, TASHA BENGOECHEA, DEBRA V. HUDSON, FIONA HARDING, SUSAN L. BERNHARD, DEBBIE JONES, ROBERT M. KAY, KAY M. HIGGINS, STEPHEN R. SCHRAMM, AND NILS LONBERG, "High-avidity human IgG-kappa monoclonal antibodies from a novel strain of minilocus transgenic mice", Nature Biotechnology, July 1996, 845-51, vol. 14.	
		ELIZABETH A. WAYNER, ROBERT A. ORLANDO, AND DAVID A. CHERESH, "Integrins alpha v beta 3 and alpha v beta 5 Contribute to Cell Attachment to Vitronectin but Differentially Distribute on the Cell Surface", J. Cell Biology, May 1991, 919-29, vol. 113, no. 4.	
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